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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,645	11/13/2001	Menzo Jans Emco Havenga	5006.1US	4875

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EXAMINER

WHITEMAN, BRIAN A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 04/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/010,645

Applicant(s)

HAVENGA ET AL.

Examiner

Brian Whiteman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-47 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-47 are pending.

Claims 27 and 47 will not be considered in the election/restriction because the examiner cannot determine what these claims encompass. Claims 27 and 47 do not contain steps or materials that would complete the pre-amble of the claims. The phrase "analyzing the nucleic acid delivery vehicle of claim 1" does not provide the steps or materials to complete the claims.

In addition, claim 31 will not be considered in the election/restriction because the examiner cannot determine what the claim encompasses. Claim 31 does not contain steps or materials that would complete the pre-amble of the claim. The phrase "administering the nucleic acid delivery vehicle of claim 1" does not provide the steps or materials to complete the claim.

If claims 27, 31, and 47 are amended in the response to the election/restriction and the examiner can determine what the claims encompass, then the examiner will consider whether the claims are directed to the elected invention or a non-elected invention.

Election/Restrictions

Restriction to one of the following inventions and an election of species is required under 35 U.S.C. 121:

- I. Claims 1-23, 28, and 38-46, drawn to an adenovirus with a tropism determinant of a fiber protein from subgroup B, classified in class 435, subclass 320.1.
- II. Claims 1, 24-26, 29, 30, and 37 drawn to a pharmaceutical preparation for the treatment of rheumatoid arthritis comprising the nucleic acid delivery vehicle of

claim 1, wherein said nucleic acid delivery vehicle comprises a gene encoding Il-10 protein, classified in class 514, subclass 44.

- III. Claims 1, 24-26, 32, 34, and 37, drawn to a pharmaceutical preparation for providing bone regeneration comprising the nucleic acid delivery vehicle of claims 1, wherein said nucleic acid delivery vehicle comprises a gene encoding bone morphogenesis protein-2 or LIM mineralization protein-1, classified in class 514, subclass 44.
- IV. Claims 1, 26, 33, and 37, drawn to a pharmaceutical composition for providing bone regeneration comprising a mesenchymal stem cell provided with a gene of interest through the nucleic acid delivery vehicle of claim 1, classified in class 424, subclass 93.21.
- V. Claims 1, 26, 35, and 37, drawn to a pharmaceutical composition for the treatment of multiple sclerosis comprising a mesenchymal stem cell provided with a gene of interest through the nucleic acid delivery vehicle of claim 1, classified in class 424, subclass 93.21.
- VI. Claims 1, 26, 36, and 37, drawn to a pharmaceutical composition for promoting angiogenesis comprising a mesenchymal stem cell provided with a gene of interest through the nucleic acid delivery vehicle of claim 1, classified in class 424, subclass 93.21.

The inventions are distinct, each from the other because of the following reasons:

Invention I and Inventions II-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Invention I is directed to an adenovirus with a tropism determinant of a fiber protein from subgroup B and Inventions II-III are directed to a pharmaceutical composition comprising a gene delivery vehicle (adenovirus, AAV, retrovirus, liposome, plasmid with an adenovirus fiber protein attached to its surface, etc.), ie. the adenoviral vector of Group I is not required. The pharmaceutical composition in Inventions II-VI is directed to treating distinct diseases. In addition, an *ex vivo* method of gene delivery set forth in Groups IV, V, and VI is not capable of use together with an *in vivo* method of gene delivery set forth in Group II and III and each method has a different mode of operation, function and effect. It would be an undue burden on the examiner to search Inventions I-VI because the search for each Invention would not overlap because of the classification for each group and/or the mode of operation, function and effect for each product is different.

Claim 1 link(s) invention I and inventions I-VI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Claims 24 and 25 link(s) invention II and invention III. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 24 and 25. Claims 26 and 37 link(s) inventions II-VI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 26 and 37. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and

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any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Because these inventions are distinct for the reasons given above and the search required for each Group is not required for any other Group and the search for each group is not co-extensive, restriction for examination purposes as indicated is proper.

It would be unduly burdensome for the examiner to search and consider patentability of all of the presently pending claims, a restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 § 1.17(h).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
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Scott D. Pribe

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER